

K070144

**Access Inhibin A Calibrators & Controls  
510(k) Summary**

**1.0 Submitted By:**

Tyler Foutch  
Regulatory Affairs Specialist  
Beckman Coulter, Inc.  
1000 Lake Hazeltine Drive  
Chaska, MN 55318  
Telephone: (952) 368-1653  
FAX: (952) 368-7610

FEB - 1 2007

**2.0 Date Submitted**

January 15, 2007

**3.0 Device Name(s):**

**3.1 Proprietary Names**

Access® Inhibin A Calibrators  
Access® Inhibin A Controls

**3.2 Classification Names**

Calibrator (21 CFR § 862.1150)  
Control (21 CFR § 862.1660)

**4.0 Legally Marketed Device**

The Access Inhibin A Calibrators & Controls claim substantial equivalence to the Diagnostic Systems Laboratories (DSL) ACTIVE® Inhibin A ELISA Calibrators and Controls currently in commercial distribution, FDA 510(k) Number K002128.

**5.0 Device Description**

The Access Inhibin A Calibrators & Controls are designed for use with the Access Inhibin A Reagent for generation of the Inhibin A assay calibration curve on Beckman Coulter's Access Immunoassay Systems. The Access Inhibin A Calibrator kit contains 7 X 2.5 mL bottles, one for each of seven calibrator levels. The Access Inhibin A Control kit contains 3 X 2.5 mL bottles, one for each of three control levels. The Access Immunoassay Systems utilize a competitive binding immunoenzymatic method for quantitative analyte measurement.

## **6.0 Intended Use**

The Access Inhibin A calibrators are intended to calibrate the Access Inhibin A assay for the quantitative determination of dimeric Inhibin A levels in human serum and plasma using the Access Immunoassay Systems.

The Access Inhibin A QC is intended for monitoring system performance of the Access Inhibin A assay.

## **7.0 Comparison to the Predicate**

The Access Inhibin A Calibrators and the predicate calibrator utilize different test methodologies, automated competitive binding immunoassay method for the Access and manual ELISA method for the DSL. The Access Inhibin A calibrators and controls are provided in Bovine Serum Albumen, while the predicate calibrator and control are provided in Fetal Bovine Serum. Both are aligned to WHO international standard 91/624. Both devices come in a liquid solution format. The Access kit contains three controls while the predicate contains two controls. The measured range differs between the two devices, the Access assay range is 0-1500 pg/mL, while the predicate range is 0-1000 pg/mL.

## **8.0 Summary of Performance Data**

The Access Inhibin A Calibrators have been demonstrated to be equivalent to the predicate product. Based on the results of the performance characteristics testing, these calibrator materials meet product claims and specifications.

Performance data from validation testing supports a finding of substantial equivalence to the Diagnostic Systems Laboratories (DSL) ACTIVE® Inhibin A ELISA Calibrators and Controls already in commercial distribution.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Tyler Foutch  
Regulatory Affairs Specialist  
Beckman Coulter, Inc.  
1000 Lake Hazeltine Drive  
Chaska, MN 55318

FEB - 1 2007

Re: k070144  
Trade/Device Name: Access Inhibin A Calibrators and QC  
Regulation Number: 21 CFR § 862.1150  
Regulation Name: Calibrator  
Regulatory Class: Class II  
Product Code: JIT, JJX  
Dated: January 15, 2007  
Received: January 18, 2007

Dear Mr. Foutch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Jean M. Cooper, M.S., D.V.M.*

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): k070144

Device Name: Access Inhibin A Calibrators and QC

Indications For Use:

The Access Inhibin A calibrators are intended to calibrate the Access Inhibin A assay for the quantitative determination of dimeric Inhibin A levels in human serum and plasma using the Access Immunoassay Systems.

The Access Inhibin A QC is intended for monitoring system performance of the Access Inhibin A assay.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

*Carol C Benson*

Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

Page 1 of   1  

K070144